



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S.

Government and is available for licensing to achieve expeditious commercialization of results of federally funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Dianca Finch, Ph.D., 240-669-5503; dianca.finch@nih.gov. Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows:

Ebola Virus Glycoprotein-Specific Monoclonal Antibodies and Uses Thereof

Description of Technology:

Ebola virus is a large, negative-strand RNA virus composed of 7 genes encoding viral proteins, including a single glycoprotein (GP). The virus is responsible for causing Ebola virus disease (EVD), formerly known as Ebola hemorrhagic fever (EHF), in humans. In particular, Bundibugyo (BDBV), Zaire (EBOV), and Sudan (SUDV) species have been associated with large outbreaks of EVD in Africa and reported case fatality rates of up to 90%. Transmission of Ebola virus to humans is not yet fully understood but is likely due to incidental exposure to infected animals. EVD spreads through human-to-human transmission, with infection resulting from direct contact with blood, secretions, organs or other bodily fluids of infected people, and indirect contact with environments contaminated by such fluids.

EVD has an incubation period of 2 to 21 days (7 days on average, depending on the strain) followed by a rapid onset of non-specific symptoms such as fever, extreme fatigue, gastrointestinal complaints, abdominal pain, anorexia, headache, myalgias and/or arthralgias.

While prior outbreaks of EVD have been localized to regions of Africa, there is a potential threat of spread to other countries given the frequency of international travel. The 2014 outbreak in West Africa was first recognized in March 2014, and as of April 13, 2016, the number of cases far exceeded the largest prior EVD outbreak with a combined total (suspected, probable, and laboratory-confirmed) 28616 cases and 11310

deaths (case fatality rate = 39.5%). The largest previous outbreak occurred in Uganda in 2000-2001 with 425 cases and 224 deaths (case-fatality rate=53%).

Viruses in the Filoviridae family are also categorized as potential threats for use as biological weapons due to ease of dissemination and transmission, and high levels of mortality. Currently, no effective therapies or FDA-licensed vaccines exist for any member of Filoviridae family of viruses.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases (NIAID) developed eight high-affinity human monoclonal antibodies, specifically EboV.YD.01, EboV.YD.02, EboV.YD.03, and EboV.YD.04, EboV.YD.05, EboV.YD.06, EboV.YD.07 and EboV.YD.08 which bind with nanomolar affinity against Ebola virus glycoprotein. The human monoclonal antibodies have been assessed by functional assays, epitope mapping, affinity measurements and in vitro neutralization assays.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. § 209 and 37 CFR Part 404.

Potential Commercial Applications:

- Prevention of acquisition of Ebola Zaire virus.
- Antibody therapy for people exposed to Ebola Zaire virus.
- Diagnostics for Ebola Zaire virus.

Competitive Advantages:

- High-affinity neutralizing antibodies (mAbs), targeting Ebola virus (EBOV) glycoprotein from a human Ebolavirus vaccine.

- Currently, there are no Food and Drug Administration (FDA)-approved vaccines or therapeutics available for prevention, post-exposure, or treatment for EBOV.
- The EboV.YD.01 - EboV.YD.08 antibodies can be combined with other biologicals and vaccines for prevention and therapy of Ebola Zaire infection/disease.

Development Stage: Preclinical Research.

Inventors: Nancy J. Sullivan, PhD (NIAID); John Misasi, PhD (NIAID).

Intellectual Property: HHS Reference Number E-061-2018 includes U.S. Provisional Patent Application Number 62/782,809, filed 12/20/2018, and PCT Application Number PCT/US2019/067423, filed 12/19/2019.

Licensing Contact: To license this technology, please contact Dianca Finch, Ph.D., 240-669-5503; dianca.finch@nih.gov.

Dated: February 4, 2020.

Wade W. Green,
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Technology Transfer and Intellectual Property Office,
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